

### REMARKS

This responds to the Office Action mailed on October 19, 2007.

Claims 1 and 34-36 are pending in this application.

#### Priority

The Examiner objected to Applicants' claim of priority under 35 U.S.C. § 119(e) to U.S. Provisional Application Serial No. 60/448,828 (the '828 application) alleging that the disclosure in the '828 application fails to provide adequate support or enablement for the subject matter of claims 34-36 as required by 35 U.S.C. § 112, first paragraph. Applicants respectfully traverse.

Claims 34-36 recite isolated variants of SEQ ID NO: 1. The claimed variant results from the substitution of an arginine with a glutamine at amino acid 525 (claim 34), substitution of a glycine with an aspartic acid at amino acid 709 (claim 35), and substitution of a serine with an asparagine at amino acid 827 (claim 36).

The '828 application discloses SIMA135, a protein of SEQ ID NO: 1. See page 3, lines 8-9. The '828 application also states that the invention encompasses SIMA135 proteins, as well as variants thereof. See page 11, lines 4-5. The '828 application states that variant proteins can have one or more amino acid substitutions. See page 11, lines 16 and 21-22. The '828 application also refers to three positions, amino acid 525, 709 and 827, and more specifically, that the amino acids at these positions are either arginine or glutamine, glycine or aspartic acid, and serine or asparagine, respectively. See page 9, line 29 to page 10, line 5. Therefore, the application supports any combination of these amino acids at amino acid positions 525, 709 and 827.

Accordingly, the subject matter of claims 34-36 is adequately supported by the '828 application and Applicants respectfully request reconsideration and withdrawal of Applicants' claim of priority.

§112 Rejection of the Claims

The Examiner rejected claims 34-36 under 35 U.S.C. § 112, first paragraph, as lacking adequate written description alleging that the specification, drawings and claims as filed disclose only a variant consisting of three amino acid changes at positions 525, 709 and 827 of SEQ ID NO: 1, and that there is no clear support for a variant consisting of a single amino acid change at position 525, 709 or 827 of SEQ ID NO: 1 as recited in claims 34-36. Applicants respectfully traverse, as support for claims 34-36 can be found in various places in the specification as filed including, for example, at page 12, lines 27 to page 13, line 1 and in the originally-filed claim 32.

The specification at page 12, lines 27 to page 13, line 1 states: "A variant of SIMA135 is intended to include a protein derived from native SIMA135 by ... substitution of one or more amino acids at one or more sites in the native protein." Thus, the specification provides support for a variant protein of SEQ ID NO: 1 (SIMA135) having one amino acid substitution.

Claim 32 as filed recites a variant of SEQ ID NO: 1 "wherein the variant has as amino acid 525 either arginine or glutamine, has as amino acid 709 either glycine [sic] or aspartic acid, and has as amino acid 827 either serine or asparagine." This claim provides explicit support for a protein of SEQ ID NO: 1 that has the following amino acid combinations at positions 525, 709 and 827, respectively: (a) arginine, glycine and serine; (b) arginine, glycine and asparagine; (c) arginine, aspartic acid, and serine; (d) arginine, aspartic acid and asparagine; (e) glutamine, glycine and serine; (f) glutamine, glycine and asparagine; (g) glutamine, aspartic acid and serine; and (h) glutamine, aspartic acid and asparagine.

Claim 34 is recites a variant of SEQ ID NO: 1 in which the amino acid at position 525 is a glutamine, and since SEQ ID NO: 1 has glycine at position 709 and serine at position 827, the variant of claim 34 is explicitly supported by originally-filed claim 32, in particular combination (e) above. Claim 35 is recites a variant of SEQ ID NO: 1 in which the amino acid at position 709 is an aspartic acid. Since SEQ ID NO: 1 has arginine at position 525, and serine at position 827, the variant of claim 35 is explicitly supported by originally-filed claim 32, in particular combination (c) above. Similarly, since SEQ ID NO: 1 has arginine at position 525 and glycine at position 709, and claim 36 recites a variant of SEQ ID NO: 1 in which the amino acid at

position 827 is asparagine, the variant of claim 36 is explicitly supported by originally-filed claim 32, in particular combination (b) above.

Accordingly, claims 34-36 is fully supported by the specification and claims as filed, and Applicants respectfully request reconsideration and withdrawal of the § 112, first paragraph, rejection of these claims.

§102 Rejection of the Claims

The Examiner rejected claim 1 under 35 U.S.C. § 102(b) as anticipated by NCBI Accession No. BAB15511, as well as by UniProtKB Accession No. Q9H5V8, alleging that each accession number inherently discloses a glycosylated protein of SEQ ID NO: 1. Applicants respectfully traverse.

BAB15511 discloses an amino acid sequence that was discovered in a human cDNA sequencing project by Watanabe et al. See BAB15511 report, page 1, REFERENCE 1 and the COMMENT section. The amino acid sequence was deduced from sequencing of the cDNA clone KAT10759. See page 2 (identifying the source of the sequence as clone KAT10759). BAB15511 does not disclose a protein isolated from signet-ring cell carcinoma cells or synthesized in eukaryotic cells.

Thus, BAB15511 provides no information whatsoever about whether or not a protein can or should be glycosylated. One of skill in the art would not necessarily conclude that glycosylation is beneficial for the activity of the protein, as is required by law for proof of inherent anticipation. An anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Here there are no factual or technical grounds supporting any allegation of inherency. Thus, the information in BAB15511 does not inherently disclose a glycosylated protein and cannot inherently anticipate claim 1.

Q9H5V8 is directed to the same information disclosed in BAB15511. For example, lines 13-15, 16, and 6, respectively, of the Q9H5V8 report indicates that Watanabe et al. submitted a sequence determined from a human cDNA sequencing project, in particular, clone KAT10759.

Q9H5V8 specifically reference the BAB15511.1 entry and its corresponding cDNA sequence AK026622 at line 22. Thus, Q9H5V8 does not inherently anticipate claim 1 for the same reasons discussed above for BAB15511.

Applicants respectfully submit that the Examiner has not provided sufficient rationale or evidence tending to show inherency. Accordingly, Applicants request reconsideration and withdrawal of the 35 U.S.C. § 102(b) rejection of claim 1.

### CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6913 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date Jan 22/08

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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 22nd day of January 2008 (Tuesday following Federal holiday).

CANDIS BUENDING

Name

Signature